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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/282,471	03/31/99	PARIKH I	121-161

HM12/0918

NIXON & VANDERHYE
1100 NORTH GLEBE ROAD
8TH FLOOR
ARLINGTON VA 22201

EXAMINER	
TRAN, S	
ART UNIT	**PAPER NUMBER**
1615	4

DATE MAILED: 09/18/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/282,471	Parikh
Examiner	**Group Art Unit**
Susan Tran	1615

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-15* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-15* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- *SEE OFFICE ACTION ON THE FOLLOWING PAGES* ---

DETAILED ACTION

Receipt is acknowledged of applicants Declaration filed 05/13/99, Information Disclosure Statement with Attachment filed 06/30/99.

Information Disclosure Statement

1. The information disclosure statement filed 06/30/99 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Objections

2. Claim 7 is objected to because of the following informalities:

Claim 7, line 3, discloses the term "phosphatidylglyerol" should read "phosphatidylglycerol". Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duclos et al. USPN 5,776,495 ('495), in view of Ecanow USPN 4,963,367 ('367).

Duclos teaches a composition comprising water-insoluble active ingredient, such as fenofibrate, surface active agents, organic solvents, and phospholipids (column 5, lines 1 through column 6, lines 1-49).

Duclos fails to specifically teach the claimed method to prepare said composition.

Ecanow teaches a composition comprising water-insoluble active ingredients (column 7, lines 25-62), surface active agents such as polyethylene glycol (column 14, lines 3-66), and phospholipids such as phosphatidyl serine, phosphatidyl choline or phosphatidic acid (column 15, lines 10-20). The composition comprising microparticles (column 17, lines 4-8), and can be used in any of the known dosage forms such as tablets, capsules, syrups, caplets, powders, and the like (column 23, lines 12-17).

The examiner notes that the cited references are silent as to the teaching of the claimed particle size values of the water-insoluble compound about 50% smaller than particles produced in the presence of phospholipid. It is the position of the examiner that no criticality is seen in the particular percentage since the prior arts obtain the same results desired by applicant, the microparticles of water-insoluble active ingredient, namely fenofibrate. The percentage has not been shown to provide any unusual and/or unexpected results over the applied references.

Furthermore, the burden would be shifted to applicant to establish that the microparticles of the cited references would not have the claimed particle size values. Thus, it would have been prima facie obvious for one of the ordinary skill in this art to prepare Duclos's fenofibrate formulation using the surface active agents and the phospholipids in view of the teaching of Ecanow to obtain a pharmaceutical dosage formulation of fenofibrate microparticles.

4. Claims 8-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duclos et al. ('495), in view of Ecanow ('367) and Haynes USPN 5,091,187.

Duclos and Ecanow are relied upon for the reasons stated above. The cited references differ from applicants claimed invention by not specifically teaching the process to prepare fenofibrate microparticles.

Haynes teaches a process to prepare water-insoluble microparticles comprising the step of size reduction by sonication, mixing drug with phospholipid and surface agent, and coating (column 11, lines 14 through column 16, lines 1-41).

Absent of showing unexpected results, it would have been prima facie obvious for one of the ordinary skill in the art to modify the composition of Duclos and Ecanow using the process of size reduction in view of the teaching of Haynes to obtain the claimed invention, because the skill artisan would have been motivated to reduce particle size by sonication.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600